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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/361,542

07/27/1999

DOUGLAS JOSEPH DOBROZSI

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27752 7590 12/12/2007

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/361,542

Applicant(s)

DOBROZSI, DOUGLAS JOSEPH

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,38,41-43,46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38,41-43,46 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of RCE, amendment and remarks all dated 9-21-07 is acknowledged.

Claims 36, 38, 41-43, 46 and 48 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-21-07 has been entered.

Instant claims 36 and 43 have been amended to recite that the composition is retained upon forming the gel-like mixture. Claim 36 also recites that the composition is an aqueous liquid.

In response to the amendment, the following is a new rejection:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 36, 38, 41-43, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,112,604 ('604) in view of US 4,680,312 ('312) and Remington's Pharmaceutical sciences, 18th edition (page 340).

'604 teaches oral, aqueous suspension formulations comprising a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water and other components (col. 1, lines 40-57 and tables 1 and 2). With respect to the drug, '604 teach addition of anti-tussive, anti-inflammatory, bronchodilator etc (col. 3, lines 47-56), similar to those claimed in the instant. '604 teach the same amount of citric acid that falls within the instant claimed range (tables). With respect to the size of colloidal silicon particles, while '604 do not mention the particle size, the reference teaches "colloidal" silicon dioxide which by definition has a particle size in the range of nanometers (admitted on page 4, lines 29-36 of instant specification). Thus, absent evidence to the contrary, the particle size of the colloidal silicon dioxide of '604 meets the claimed range. '604 teach oral suspension that read on the claimed method of administering a medicament by swallowing the composition. '604 fail to specify the amount of water in the composition. However, both the examples of '604 recite ingredients that include water in the simple syrup preparation (col. 6, lines 14-20 and claim 1). Accordingly, absent unexpected advantage with the claimed high amounts of water, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include the appropriate amount of water to prepare an oral aqueous liquid composition comprising the claimed active agent, silicon dioxide and

citric acid, without losing the therapeutic efficiency of the drug as well as the stability afforded by silicon dioxide.

With respect to the amount of silicon dioxide of instant claims 38 and 44, '604 teach up to 2% and not the claimed percentage. However, instant claims recite a wide range of "about 3% to about 50%" that includes very low and very high amounts.

'312 teach stable gels of prostaglandin comprising silicon dioxide as a gel forming agent. '312 teaches that the use of colloidal silicon dioxide as a gelling agent is known in the art and teaches that the silicon dioxide is included in the composition in an amount of 3-15% and teaches that lower percentage of silicon dioxide results in lower viscosity (col. 2, L 60 through col. 3, L 19, col. 4, L 23-30 and col. 5, L 14-36).

Remington's Pharmaceutical Sciences teach that colloidal silicon dioxide is used to prepare gels and are employed as thickeners (page 340, col. 2).

Thus, the ability of colloidal silicon dioxide to form a gel is well recognized in the prior art cited. The prior art ('312) further teaches silicon dioxide in the same amount range as claimed in the instant invention and further teaches that the amount should be such that it induces free flowing gel. '312 further states that lower amounts of silicon dioxide renders low viscosity gels and that a minimum amount is necessary to achieve the minimum desired viscosity to the selected liquid.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that silicon dioxide of '604 still possess the

ability to form a gel at the amounts taught by the reference, even though having lower viscosity. In this regard, while the prior art recognizes the gel forming ability at lower amounts of silicon dioxide, applicants have not shown otherwise. '620 teach hydrocolloid silicon dioxide which by nature form gels even though the '620 teaches the compound for preparing stable suspensions. Further, it would have been obvious for a skilled artisan at the time of the instant invention that the colloidal silicon dioxide of '620 not only acts as a suspending agent but also acts as a thickener or gel forming agent ('312 and Remingtons') depending on the amount of colloidal silicon dioxide employed. Given the teachings of prior art that the claimed compound forms gel a skilled artisan would have expected that the composition of '620 upon administration would possess the claimed muco-retentive properties and in the absence of any unexpected advantage, one of an ordinary skill in the art would have been motivated to optimize the amount of silicon dioxide in the composition of '604 because '604 suggest that colloidal silicon dioxide imparts stability to the suspension so as to remain stable in suspension for a long time and '312 teaches that the same compound induces free flowing gels and also recognizes that colloidal silicon dioxide is routinely employed oral formulations (col. 4, L 23-30).

Response to Arguments

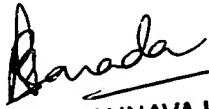
Applicant's arguments with respect to instant claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
December 10, 2007


LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER